

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

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| IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION | Master File No. 2:12-MD-02327 MDL 2327 |
| THIS DOCUMENT RELATES TO: WAVE 3 CASES | JOSEPH R. GOODWIN U.S. DISTRICT JUDGE |

**DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE
THE OPINIONS AND TESTIMONY OF SCOTT A. GUELCHER, PH.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”) submit this Reply in Support of their Motion to Exclude the Testimony and Opinions of Scott A. Guelcher, Ph.D. [Doc. 2852 (“Mot.”)] and Memorandum of Law in Support [Doc. 2853 (“Mem.”)], (collectively, “Motion”).

To the extent that Plaintiffs’ Response to the Motion [Doc. 2937 (“Response”)], incorporates by reference their Wave 1 *Daubert* Response [Doc. 2164], Ethicon incorporates by reference its Reply in Support of its Motion to Exclude the Testimony and Opinions of Scott A. Guelcher, Ph.D. [Doc. [2210].

Because Plaintiffs also asserted certain additional responses, Ethicon submits the following reply.

I. Plaintiffs’ Experts Have Confirmed That Prolene Is Unique From Other Forms of Polypropylene.

In its Motion, Ethicon explained that Plaintiffs’ materials science experts—including Dr. Guelcher—have admitted under oath that Prolene is chemically distinct from other forms of

polypropylene, including commercially available formulations. *See* Mem. at 2-4 (quoting testimony by Dr. Guelcher, as well as Plaintiffs other materials science experts, Dr. Jimmy Mays and Dr. Duane Priddy). Specifically, Ethicon showed that Plaintiffs' materials scientists agreed that the singularity of Prolene is due to its unique additive package, including a proprietary blend of antioxidants that retard oxidation *in vivo*. *See id.* On this basis, Ethicon argued that Dr. Guelcher's reliance on studies that do not involve Prolene renders his opinions about Prolene unreliable. *See id.* at 9-14.¹

Notably, Plaintiffs have not disputed the concessions made by their experts. *See generally* Pls.' Resp. to Defs.' Mot. to Exclude the Testimony of Dr. Guelcher, Ph.D. [Doc. 2164]; Pls.' Resp. to Ethicon's Mot. to Exclude or Limit the Opinions and Testimony of Dr. Scott Guelcher [Doc. 2937].

Instead, Plaintiffs point to this Court's prior rulings that Ethicon's position is "wholly conceived by lawyers, [and] unfounded in science." Resp. at 2 (quoting *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014) & Mem. Op. and Order (*Daubert* Motion re: Scott Guelcher, Ph.D.), at 9 [Doc. 2698]).

Ethicon is certainly aware of the Court's prior orders, but it nonetheless respectfully submits that a proposition to which Plaintiffs' materials science experts have now *agreed* cannot be considered solely the product of Ethicon's attorneys' imaginations or divorced from the principles of science. This Court has said that each motion must stand on its own foundation, and Ethicon has now provided the foundation for its distinction. Ethicon respectfully submits that the Court should distinguish its prior ruling on this basis.

¹ Although Dr. Guelcher also points to certain internal Ethicon documents to support his opinions, Ethicon explained in its Motion that tests on which Dr. Guelcher relies simply do not support his opinion that the Prolene used in Ethicon mesh products is subject to scientifically significant oxidation or degradation in the human body. *See* Mem. at 14-15.

II. Dr. Thames's Opinion That Prolene Is Not Subject To Scientifically Significant Oxidation or Degradation *In Vivo* Does Not Support Plaintiffs' Position.

Plaintiffs attempt to support their argument by pointing to the Court's ruling that Dr. Thames cannot testify that Ethicon's dog study "showed no losses in molecular weight" because the study "reported no significant difference in molecular weights[.]" Resp. at 2. But Plaintiffs ignore the fact that Dr. Thames's opinion—which is well-documented throughout his expert report—actually is that the study reported no "significant" or "meaningful" change in molecular weight. *See, e.g.*, Reply Ex. DD, Expert Report of Shelby F. Thames, Ph.D., at 6 (Aug. 8, 2016) ("The seven year data confirmed no significant difference in molecular weights for the 4/0 Prolene control suture and the seven year explants.").²

In other words, the Court's Order does not affect the opinion Dr. Thames will offer at trial, or his opinion that Prolene is not subject to scientifically significant or meaningful oxidation or degradation in the human body. Nor does it constitute scientific evidence contradicting the fact that Prolene has a unique chemical formulation due to its additive package. Plaintiffs' suggestion to the contrary is meritless.

III. Dr. Guelcher's Failure To Test Prolene Renders His Degradation Opinions Unreliable Because None Of The Studies Or Internal Ethicon Documents On Which He Relies Actually Supports His Opinions.

Finally, Plaintiffs claim that Ethicon has erred by "insisting that 'Dr. Guelcher should be required to testify regarding his [unfinished] study,' even though the Court previously found that

² *See also id.* at 8 (explaining that "Burkley [an Ethicon scientist] performed molecular weight determinations . . . and found no meaningful change over the 7 years of implantation."); *id.* at 9 (explaining that the "physical property/toughness data" reported in the dog study "confirms no meaningful loss in molecular weight"); *id.* ("These data are consistent with no meaningful molecular weight changes having occurred during 7 years implantation."); *id.* ("Had Burkley or plaintiff's expert found any significant molecular weight loss, tensile strength, elongation, and toughness properties would have declined precipitously."); *id.* at 10 ("Prolene's molecular weight did not change significantly over the 7 years of implantation."); *id.* at 30 ("[P]roperty altering molecular weight changes did not occur *in vivo*.").

his testing is unreliable, because “there is no requirement under *Daubert* for an expert to rely on any case-specific testing.” Resp. at 3. Plaintiffs misunderstand Ethicon’s arguments.³

Ethicon does not “insist[]” that Dr. Guelcher testify about his “unfinished” and unreliable testing, as Plaintiffs suggest. Rather, Ethicon observed that because Dr. Guelcher no longer relies on this testing, he admits that testing could be done, yet he has no tests on Prolene which could furnish the basis for the opinions he seeks to offer in this litigation. Mem. at 7.

Moreover, as the Motion clearly demonstrates, Ethicon does not claim that testing is a precondition to the admissibility of all expert testimony. *See id.* at 8. Instead, Ethicon observed that courts have found testing to be highly probative of the reliability of an expert’s opinions. *See id.* Ethicon noted that this is particularly true where—as is the case with Dr. Guelcher—the only other support on which the expert relies does not actually address the subject at issue in the case. *See id.* at 8-15.

Thus, because Dr. Guelcher cannot rely on any testing on Prolene, and none of the literature on which he relies supports the proposition that Prolene is subject to oxidative degradation *in vivo*, Ethicon submits that Dr. Guelcher’s opinions regarding Prolene should be excluded as unreliable. *See Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 249 (4th Cir. 1999).

IV. Conclusion

For these reasons, as well as those articulated in Ethicon’s Motion, Ethicon respectfully requests that the Court grant its Motion to Exclude the Opinions and Testimony of Dr. Scott Guelcher.

³ Plaintiffs appear to misunderstand Dr. Guelcher’s testing, as well. Dr. Guelcher’s test was not “case-specific testing” as Plaintiffs suggest. Resp. at 3. Rather, Dr. Guelcher conducted a test on a pristine Prolene mesh exemplar to determine whether Prolene “can oxidize and degrade under oxidative conditions similar to those experienced in the human body after implantation.” Mot. Ex. G, Guelcher 12/18/14 Dep. 123:25-124:8.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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